Remarks

Claims 1 – 82 were original in the application. Claims 83 – 92 were added by preliminary amendment. Claims 1, 7, 13 – 28, 33 – 36, 42 – 52, 54, 57, 61 – 69, 76 – 89 and 92 were withdrawn from consideration by restriction. Claims 1, 13 – 28, and 83 – 89 are cancelled without prejudice. Objection was made to claims 32, 39, 41, 53, 72 – 75 and 90 – 91 which were rewritten to stand in independent form and are submitted as allowable. Claims 2 – 6, 8 – 12, 29 – 31, 37, 38, 40, 55, 56, 58 – 60, 70 and 71 were rejected on art. Claims 2, 29, 32, 39, 41, 53, 72 - 75, 90, and 91 are currently amended. Therefore, applicant requests that claims 2 – 6, 8 – 12, 29 – 31, 37, 38, 40, 55, 56, 58 – 60, 70 and 71 be substantively examined and that claims 2 – 12, 29 – 82, and 90 – 92 be advanced to issuance.

Rejection Pursuant to 35 USC 102(b)

Claims 2, 6, and 8 - 12 were rejected as being anticipated by **Slater,** *"One Piece Vessel Dilator/Catheter Sheath Introducer,"* US Patent 5,395,341 (1995). **Slater** was cited by the Examiner for disclosing a catheter sheath introducer that includes a moldable sheath (see 3:26-32) with a lumen (22). The Examiner further characterized **Slater** as showing a sheath has a sealing valve (14) with a distal portion of the sheath is made from a different material that has both different stiffness and different moldablility from the proximal portion. The distal portion of the sheath will have been altered before implantation into the body in order to have shape memory upon contact with the temperature of the body.

Once inserted into the body the distal portion will change shape in reaction to the temperature of the body (see figures 2-3).

Slater *does not disclose* a sheath with is moldable at body temperatures to at least temporarily retain a specific shape imparted to it as required by claim 2. At col. 3:26-32 **Slater** actually teaches away by stating that the sheath ". . . *does not change shape with changes in temperature above and below the typical human body temperature of 98.2 F.°.*." (emphasis added). At col. 3:33 – 40 **Slater** states that the sheath ". . . has a temperature dependent memory and which changes shape when the temperature thereof is increased to body temperature from a first tapered shape 31, as shown in FIGS. 1 and 2, to an expanded shape 32, as shown in FIG. 3." As stated in the abstract of **Slater** the sheath has a ". . . tapered distal portion which is made of a material that has a temperature dependent memory and which changes shape when the temperature thereof is increased to body temperature so that the tapered distal portion can change from its first tapered shape to an expanded generally cylindrical shape with a diameter close to the diameter of the proximal portion."

Slater is a stiff sheath which is not moldable at all, but which has a distal portion which expands in diameter when it is put into the body. Hence the sheath has a tapered shape when first inserted into the body for ease of insertion and then it expands to be nontapered or cylindrical to each of disposing catheters through it. The fact that a portion of the sheath expands in diameter to change its diameter does not in any sense mean it is moldable. In fact, it is more likely and we can assume that the expanded tip is a stiff as the proximal portions at all

times.

Slater discusses a temperature dependent memory of a diameter only. The memory of the material of the claimed invention is not necessarily temperature dependent. Moreover, when **Slater** discusses memory shape, he is referring only to the diameter of the sheath which is strictly controlled by temperature, and not to any kind of a shape imparted to the sheath by the surgeon. **Slater** never discloses or discusses user-moldability or even just moldability of the sheath with respect to the three dimensional disposition of the sheath.

Slater has nothing to do with a user-moldable sheath which retains a memory of its imparted shape as claimed and does not anticipate the subject matter of claims 2, 6, 8-12 as amended.

Thus, it cannot be sustained that each and every element of claims 2, 6, and 8 – 12 are disclosed by **Slater.**

Rejection Pursuant to 35 USC 102(e)

Claims 2 - 6, 8 - 12, 29 - 31, 37 - 38, 40, 55 - 56, 58 – 60 and 70 - 71 were rejected as being anticipated by **Kratoska et al,** *Expandable Introducer Sheath,"* US Patent 6,090,072 (2000). The Examiner cites **Kratoska** for disclosing an expandable introducer sheath that includes a moldable sheath with a lumen and a shaping tool (mandrel) that is separate from the sheath but incorporated into the lumen of the sheath, see figure 2B. The Examiner contends that it can be considered that as shown in figures 3B-3D, as the mandrel is introduced into the

sheath, the sheath will have different portions having different stiffness and moldability depending on how far into the sheath the mandrel has been advanced, see figure 3C. Since the sheath is moldable by the mandrel the sheath can be molded before, during or after the sheath is inserted into the body cavity.

As stated in the abstract of **Kratoska** ". . . the sheath is made of a shape-memory polymer and is manipulated by inserting a heated mandrel (with an outer diameter larger than the inner diameter of the sheath) within the sheath to cause the sheath to expand to an inner diameter at least approximately equal to an outer diameter of the mandrel. . . ."

The sheath is relatively stiff or unmoldable in that its shape can be changed only by the insertion of a heated mandrel. What **Kratoska** discloses is that the sheath ". . . is made of a shape-memory polymer and before placement within the vessel, the sheath is mechanically "formed down" to have an inner diameter smaller than the original size inner diameter formed when the sheath was extruded. Once in the vessel, the sheath can be manipulated to expand its inner diameter back to the original size. To do so, a heated mandrel can be inserted into the sheath to cause the sheath to exceed a glass transition temperature of the polymer material and thereby induce the shape-memory polymer material sheath to "snap back" to its original and larger size inner diameter."

Again diameter of the sheath is being discussed and not any overall three dimensional shape of the sheath. **Kratoska** never discloses or discusses user-

moldability or even just moldability of the sheath with respect to the three dimensional disposition of the sheath. Also only that portion in thermal contact with the heated mandrel can even changed diameter. The portions of the introducer distal to the introducer remain unaffected in all respects.

Thus, it cannot be sustained that each and every element of claims 2 - 6, 8 - 12, 29 - 31, 37 - 38, 40, 55 - 56, 58 – 60 and 70 – 71 are disclosed by **Kratoska.**

The applicant respectfully requests advancement of the claims to issuance.

Respectfully submitted,

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